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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/923,327	08/08/2001	Patricia D. Murphy	044921-5054-02	3339

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EXAMINER	
MYERS, CARLA J	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 02/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	09/923,327	MURPHY, PATRICIA D.	
	Examiner	Art Unit	
	Carla Myers	1634	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 21 January 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on *21 October 2004*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☒ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☒ Newly proposed or amended claim(s) *97-100,103,105-110,115-117,122 and 123* would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *97-101,103 and 105-124*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

Continuation of 3. NOTE: The amendments to the claims raise new issues under 35 U.S.C. 112 first paragraph (New Matter) and 35 U.S.C. 112, second paragraph. Specifically, the amendment raises new issues under 35 U.S.C. 112 second paragraph with respect to claim 101 because the recited nucleotide variations listed in claim 97 are defined in the specification as occurring in the BRCA1 coding region. Yet claim 101 refers to nucleotide variations present in the intron region. Thereby, it is not clear as to how claim 101 is intended to be further limiting from claim 97 and it is not clear as to whether claim 101 intends to refer to the same nucleotide variations set forth in claim 97 or to a different set of nucleotide variations. The amendment to limit the claims to the detection of omi1 by detecting a nucleotide variation at positions 2201, 2731,2430,4427, 3232, 3667 and 4956 in a nucleotide sequence from an individual with a family history which indicates a predisposition to breast cancer wherein the presence of the stated nucleotide variations indicates the omi1 haplotype raises the issue of New Matter with respect to claims 111-114 and 118-121. The specification as originally filed (e.g., page 22) teaches determining the sequence of individuals who are classified as being at low risk of susceptibility to breast cancer and comparing the sequence form these individuals to a reference sequence in order to determine a haplotype. The specification teaches performing this method using 5 or more samples. The specification teaches methods in which the sequence of individuals who have a family history of breast cancer are analyzed to determine whether the individual's have the omi1 haplotype. The specification also teaches methods in which nucleic acids from 47 individual's taking tamoxifen to prevent breast cancer or the reoccurrence of breast cancer are sequenced and compared to the omi1 consensus sequence (see, e.g., page 35-36). However, the specification does not appear to provide support for methods which specifically require the analysis of nucleic acids from 2 or 10 or 50 or more individuals having a family history of predisposition to breast cancer in order to detect the stated nucleotide variations as indicative of the omi1 haplotype. There does not appear to be support in the specification for applying the method as claimed to a specific group of 2 or 10 or 50 or more individuals. Lastly, the amendment raises the issue of new matter with respect to claim 124. Claim 124 requires that the "determined omi1 haplotype of the human BRCA1 gene is associated with a predisposition to developing breast cancer." However, the specification teaches (pages 2 and 32-33) that the consensus omi1 haplotype represents the "normal" or "wildtype" sequence. Thereby, the specification does not provide support for the concept that the omi1 haplotype is associated with predisposition to breast cancer. Rather, the specification teaches that the omi1 haplotype is not associated with a predisposition to developing breast cancer.

Continuation of 11. does NOT place the application in condition for allowance for the reasons of record in view of the non-entry of the after final amendment. It is noted, however, that the proposed amendment would overcome the rejections under 35 U.S. C. 112 first and second paragraphs and the objection to the specification as set forth in the prior Office action of 4/21/2004. Further, in the response of 1/21/2005, Applicants request that the obviousness-type double patenting rejection "be held in abeyance until a finding of allowable subject matter is made by the Examiner with the understanding that Applicants can file a terminal disclaimer at a later date." However, it is not the Office's policy to hold rejections in abeyance. It is not clear from Applicants response as to whether Applicants intend to file a terminal disclaimer or whether Applicant's are acknowledging the option to file a terminal disclaimer, but are not actually agreeing to file such a terminal disclaimer. A proper response requires that Applicants fully address all outstanding rejections .

CARLA J. MYERS
PRIMARY EXAMINER